UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS

No. 6:22-cv-00429

Vapor Train 2 LLC et al.,
Plaintiffs,
v.
U.S. Food and Drug Administration et al.,
Defendants.

OPINION AND ORDER

This case concerns e-cigarette regulatory approval. Plaintiffs move for initial injunctive relief before the merits of the case are decided with finality. For the reasons explained below, plaintiffs' motion for that relief (Doc. 7) is denied.

1. The Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as amended at 21 U.S.C. §§ 387–387v), regulates "tobacco products." Now included among those "tobacco products" are e-cigarettes made with synthetic nicotine, such as the ones at issue here. 21 U.S.C. § 321(rr)(1) (now including products "containing nicotine from any source").

The Tobacco Control Act prohibits the manufacture, delivery, or receipt in interstate commerce of any tobacco product that is "adulterated." *Id.* § 331(a), (c), (g). Adulteration occurs if the product "is required by section 387j(a) of this title to have premarket review and does not have an [approval-of-marketing] order in effect under section 387j(c)(1)(A)(i)." *Id.* § 387b(6)(A). That prohibition is enforceable by the seizure of adulterated products and the imposition of a sentence of imprisonment, a fine, and an injunction. *Id.* §§ 332(a), 333(a), 334(a).

Section 387j requires, with certain exceptions, that any new tobacco product undergo a premarket review. *Id.* § 387j(a)(2). The statute lists some requirements for a premarket tobacco product

application (a "PMTA" or "application") and gives the Secretary of Health and Human Services authority to impose additional application requirements by regulation. *Id.* § 387j(b).

2. One such regulation, 21 C.F.R. § 1114.27, dictates the procedure for review of a PMTA. First is an initial decision on whether to "accept" the PMTA for further review—the step at issue here:

> (1) After an applicant submits a PMTA, FDA will perform an initial review of the PMTA to determine whether it may be accepted for further review. FDA may refuse to accept an application that:
>
> > (i) Does not comply with the applicable format requirements in § 1114.7(b) . . . ;
> >
> > (ii) . . . [D]oes not appear to contain the information required by § 1114.7 . . . ; or
> >
> > . . .
> >
> > (iv) FDA can otherwise refuse to accept under § 1105.10.

Id. § 1114.27(a)(1). Each of those cross-referenced authorities for a refusal to accept are relevant here.

Section 1114.7 gives a host of requirements for ultimate approval of a PMTA. They include a required certification of truthfulness. *Id.* § 1114.7(m). An application that does not appear to contain that certification may thus be refused under § 1114.27(a)(1)(ii).

The "format requirements in § 1114.7(b)" are also made, under the regulation just quoted, requirements for initial acceptance of a PMTA. The application must be "written in English" using "the form(s) that FDA provides." *Id.* § 1114.7(b)(1). And any included "[d]ocuments that have been translated from another language into English" must be accompanied by the "original language version of the document" and a certificate of translation. *Id.*

Section 1114.7(b) does not itself say when a document must be translated from a foreign language into English. Instead, that is dictated by 21 C.F.R. § 1105.10. It states that the FDA will "refuse to accept" an application if the "submission is not in English or does not contain complete English translations of any information

submitted within." *Id.* § 1105.10(a)(2). Language is "information"—an "organized means of conveying or communicating ideas." *Language*, Black's Law Dictionary (11th ed. 2019). So if an author writes the original version of a document in both English and a foreign language, the foreign-language portions of the document require a "complete English translation." When a document is translated into English for submission, in turn, § 1114.7(b)(1) requires a translation certificate to accompany the translated document.

The FDA will also refuse to accept a PMTA if the "submission does not contain a required FDA form(s)." 21 C.F.R. § 1105.10(a)(6). Three such forms are relevant here:

- Form 4057 is required when submitting a PMTA for any tobacco product. FDA, *Premarket Tobacco Product Applications and Recordkeeping Requirements*, 86 Fed. Reg. 55,300, 55,403 (Oct. 5, 2021).
- Form 4057b is required when applicants "submit a single premarket submission for multiple products (i.e., a bundled PMTA)." 86 Fed. Reg. at 55,317. Form 4057b is an Excel file used to organize the data for each individual product in the bundled submission. *Id.* at 55,404; FDA, *Form 4057b*.
- Form 4057a is required when "submitting amendments and other general correspondence." *Id.* Among other things, the form calls for the reason for amendment and a certification of truthfulness under 21 C.F.R. § 1114.7(m). FDA, *Form 4057a*.

As to process, if the FDA "refuses to accept an application, FDA will issue a letter to the applicant identifying the deficiencies, where practicable, that prevented FDA from accepting the application." 21 C.F.R. § 1114.27(a)(3). The applicant remains free to submit a new, updated application. FDA, *Refuse to Accept Procedures for Premarket Tobacco Product Submissions*, 81 Fed. Reg. 95,863, 95,864 (Dec. 29, 2016) ("FDA's refusal to accept a tobacco product submission does not preclude an applicant from resubmitting a new submission that addresses the deficiencies."). On the other hand, if the FDA accepts an application for review, it will "issue an acknowledgement letter to

the applicant that specifies the PMTA STN." 21 C.F.R. § 1114.27(a)(2).

That "STN" is the "submission tracking number." Nothing precludes the FDA from assigning an STN upon receipt of a PMTA. But the regulations require the FDA to provide an STN only after an application is accepted: "FDA will send to the submitter an acknowledgement letter stating the submission has been accepted for processing and further review and will provide the premarket submission tracking number." *Id.* § 1105.10(b).

After a PMTA is accepted for review, the FDA then performs a review of whether the application has enough information for a final, substantive determination on marketing approval. *Id.* § 1114.27(b). If it does not, the FDA may "refuse to file" the accepted application and will send the applicant a letter noting the deficiencies that prevented the "filing" of the application. *Id.* § 1114.27(b)(1), (2). Otherwise, if an application is an "application under subsection (b)" of 21 U.S.C. § 387j, the Secretary must grant or deny approval to the new tobacco product within 180 days from the receipt of the application. 21 U.S.C. § 387j(c)(1)(A).

Once an application is "pending," an applicant may amend the application of its own accord or to respond to agency notices. 21 C.F.R. § 1114.9(a). Any such amendment must "specify the STN assigned to the original submission." *Id.* That regulation does not define "pending." But it does equate a "pending PMTA" with a PMTA that can be "withdraw[n] . . . under § 1114.11." *Id.* § 1114.9(c). And that provision allows an applicant to "withdraw a PMTA that FDA has not acted on as described in § 1114.29," *id.* § 1114.11(a), which allows the FDA, after "receipt of an application," to "refuse to accept the application as described in § 1114.27(a)." *Id.* § 1114.29(a). So § 1114.9(a) allows an applicant to amend a PMTA as soon as it is received by the FDA, even if it has not been "accepted" and thus even if an STN is not required to have been assigned. If an STN was not provided by the time of amendment, there would be no "STN assigned to the original submission."

3. The Act's definition of "tobacco products" was recently expanded to include products with synthetic nicotine. The effective date of that statutory amendment was April 14, 2022. Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, Div. P, § 111(c), 136 Stat. 49, 789 (2022). That expansion was accompanied by a safe-harbor transition period for previously marketed products that had not required premarket review. *Id.* § 111(d). If a manufacturer applied for market approval by May 14, 2022, it could continue to market the products until July 13, 2022. *Id.* § 111(d)(2). For commerce on or after that date, an order approving the product under § 387j is required. *Id.* § 111(d)(3).

4. Plaintiff Magellan is a New York corporation that distributed Hyde and JUNO brand e-cigarettes, which contain synthetic nicotine. Doc. 1 at ¶ 4. Plaintiff Vapor Train 2 is a Texas retailer that sold those e-cigarettes at its stores in this judicial district. *Id.* at ¶ 5. Plaintiffs sue the FDA and its commissioner, as well as the Department of Health and Human Services and its head, alleging that the FDA violated the Administrative Procedure Act by issuing a "refuse to accept" order for Magellan's PMTAs.

Plaintiffs move for initial, injunctive relief directing the FDA to disregard its refuse-to-accept order and continue processing Magellan's PMTAs. In deciding this motion, the court finds the facts stated below from the verified complaint, the declarations, and the exhibits.

On May 12 and 13, 2022—before the application deadline allowing a temporary safe harbor from the expanded "tobacco products" definition—Magellan submitted eleven bundled PMTAs. Some of the PMTAs included, among other supporting documents, quality-

5.10 量规、仪器日常维护

Daily maintenance of gauges and instruments

5.10.1 品管部制定对应仪器的日常点检与维护内容，将点检内容加入《设备/设施保养点检记录表》，经文控下发使用部门进行日常的点检。

The Quality Control Department shall formulate the daily spot inspection and maintenance content of corresponding instruments， add the spot inspection content into the "EquipmentFacilities maintenance spot inspection record"， and issue it to the user department for daily spot inspection through the Document Control Center.

5.10.2.精密仪器则由指定人员进行定期保养，如厂内无法保养则由原制造厂商到厂内进行保养作业。

5.11 仪器设备的搬运与防护要求

Transport and protection requirements of instruments

control and manufacturing documents originally written in two languages: Mandarin and English. Doc. 1 at 10. A sample from one of those dual-language documents follows:

The English text shown above may be translations of the Mandarin text. But that is not clear. For one, some Mandarin text like that in paragraph 5.10.2 is not followed by English text. More broadly, the applications did not identify the English text as a "complete English translation" of the Mandarin text, as by including a certificate of translation for the Mandarin text. 21 C.F.R. § 1105.10(a)(2).

Magellan submitted its PMTAs through two contractors:

- Ten of the eleven PMTAs were submitted by a contractor named Skyte, using the FDA's Center for Tobacco Products portal. That portal did not generate an STN for the applications. The FDA's website recommends using that portal, although the website offers an alternative option of using an agency-wide Electronic Submissions Gateway.
- The eleventh PMTA was submitted by a contractor named Accorto, using the FDA's Electronic Submissions Gateway. That gateway provided an STN when the eleventh PMTA was submitted.

Doc. 1 at 8–9.

On July 8, 2022, an Accorto employee asked the FDA ombudsman's office to provide the STNs assigned to the Skyte submissions. Doc. 26 at 5 (Angelico Decl.). On July 19, 2022, the FDA replied with a list of STNs assigned to all eleven of Magellan's PMTAs but did not identify which STN corresponded to which PMTA (which the Accorto employee had not asked the FDA to do). *Id.* at 4–5. The preliminary-injunction record has no evidence that Magellan or its contractors followed up with the FDA to correlate individual STNs to individual PMTAs.

At some point, Magellan apparently realized that it needed to include Form 4057b for the ten bundled PMTAs that Skyte uploaded. The record is somewhat unclear, however, on how many of the ten PMTAs Magellan attempted to amend. Declarations by a Skyte

employee attest to nine amendments submitted on August 18, 2022. Doc. 7-1 at 2 (Huang Decl.). The employee confirms that the nine amendments included a Form 4057b for each PMTA and a Form 4057a giving the purpose of each amendment. *Id.* On the other hand, the verified complaint implies that ten amendments (not nine) were submitted, stating: "On August 18, 2022, SKYTE uploaded supplemental amendments for each bundled PMTA it had originally submitted," of which there were ten. Doc. 1-1 at 9. Comparing the file names and products from the exhibit showing the Skyte employee's August 18 submissions begs the question whether an amendment for the "Hyde X Kit" product was ever submitted. At this stage, the court will accept the verified complaint's attestation that ten amendments were submitted, one for each of the PMTAs that Skyte originally submitted. But defendants are free to move for discovery or sanctions if that sworn attestation is believed to be incorrect.

After the FDA's July 19, 2022 email, Magellan knew that there was an "STN assigned to the original submission" for each PMTA. But Magellan did not follow up with the FDA to correlate individual STNs to PMTAs. That led to Magellan submitting the amendments without providing an STN for any PMTA. Instead, Magellan put information in the names of the zipped files containing the amendments, as would allow linking them to the original PMTAs. Doc. 7-1 at 3.

On October 6, 2022, the FDA refused to accept all eleven of Magellan's pending PMTAs. Doc. 1-1 at 2–3. That order is the agency action challenged here. It is based on three asserted deficiencies.

The first two deficiencies concern the ten PMTAs submitted by Skyte, which were faulted for (1) not using Form 4057b, as required for bundled PMTAs, and (2) not including the certification of truthfulness described in 21 C.F.R. § 1114.7(m). Those two issues would apparently have been resolved by the amendments submitted by Skyte, which contained Form 4057b (curing issue 1) and Form 4057a (which included a certification of truthfulness, curing issue 2). But the FDA rejected those amendments for two reasons:

- One of the amendments allegedly lacked Form 4057a and therefore failed to use the amendment form required by the FDA, as directed by § 1114.9. *Id.* at 3.
- The "remaining amendments" did not specify the STNs assigned to the original PMTAs. *Id.* Although that deficiency was not noted for the first amendment (perhaps because it was rejected for another reason), it is now undisputed that all of the amendments did not include STNs. Doc. 7-1 at 2–3 (stating that the zipped file names were used instead to identify the relevant PMTA).

With the attempted amendments disregarded, the FDA refused to accept Magellan's ten PMTAs submitted by Skyte based on the two deficiencies noted above. Doc. 1-1 at 2–3.

The third deficiency concerns the dual-language documents submitted with two of the PMTAs (including the one submitted by Accorto). The FDA acknowledged that the documents appear to contain an "English translation" alongside Mandarin passages. *Id.* at 3. But the FDA observed that it could not ensure that the apparent English translations are "complete" and "accurately reflect the content of the original documents," as required, because Magellan had not certified the accuracy of any translation. *Id.* at 3.

The FDA's refuse-to-accept order ends by directing Magellan that it cannot introduce into interstate commerce the synthetic-nicotine e-cigarette products covered by the PMTAs. *Id.* at 4. In response, Magellan considered submitting new, revised PMTAs. But Magellan perceives irreparable injury in proceeding that way because it would not preserve the May 12 and 13 original application dates, which fell before the deadline for the temporary safe harbor mentioned above. Of course, that safe harbor is no longer operative, having expired two months later on July 13. But Magellan still perceives irreparable injury in being deprived of an argument to the FDA for non-enforcement discretion in light of the original application dates. Doc. 1 at 13. Based on that asserted irreparable injury, plaintiffs now move for injunctive relief.

5. Opposing that relief, the FDA first argues that Vapor Train lacks Article III standing. But the parties do not contest that co-plaintiff Magellan has standing to challenge the agency's order refusing to accept its PMTAs. And "[i]f at least one plaintiff has standing, the suit may proceed." *Biden v. Nebraska*, 143 S. Ct. 2355, 2365 (2023) (citing *Rumsfeld v. FAIR, Inc.*, 547 U.S. 47, 52 n.2 (2006)). Binding Fifth Circuit precedent holds that "the presence of one party with standing is sufficient" to authorize judicial relief for all plaintiffs challenging the same defendant's actions on the same legal theory—what the Fifth Circuit calls the same "claim." *Brackeen v. Haaland*, 994 F.3d 249, 291 (5th Cir. 2021) (en banc), *aff'd in part*, *rev'd in part on other grounds*, 143 S. Ct. 1609 (2023). Here, Vapor Train challenges the same agency action under the same legal theories as does Magellan, whose standing is undisputed. As such, Vapor Train's challenge is, under circuit precedent, within the same "case or controversy" entrusted to this court's jurisdiction.

6. To win preliminary injunctive relief, plaintiffs carry the burden of showing that (1) they have a substantial likelihood of success on the merits of their claim; (2) they will suffer irreparable harm without an injunction; (3) the balance of equities tips in their favor; and (4) relief is not contrary to the public interest. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997); *Brock Servs., L.L.C. v. Rogillio*, 936 F.3d 290, 296 (5th Cir. 2019). Because the administrative record has not been certified, the court must decide the likelihood of success on the APA claim based on the likely contents of the administrative record, established by sources cited above.

Several predicates to plaintiffs' success are not disputed. Sovereign immunity is waived by the APA because plaintiffs seek only non-damages relief from federal agencies and officials. 5 U.S.C. § 702. The form of action is proper because there is no special statutory review proceeding for this matter. The Fifth Circuit thus dismisses direct appeals to that court from FDA refuse-to-accept orders. *E.g.*, *Boomtown Vapor, LLC v. FDA*, No. 22-60467 (5th Cir. Nov. 1, 2022) (order granting motion to dismiss). And the APA grants a right of judicial review of the agency action here: There is no other adequate

remedy in a court (Fifth Circuit direct review being unavailable, and damages remedies being barred by sovereign immunity). 5 U.S.C. § 704. And the refuse-to-accept order is "final" agency action because it is the culmination of the agency's assessment of whether Magellan's PMTAs meet the requirements to be accepted for further review. *Id.*

So plaintiffs' likelihood of success turns on whether the refuse-to-accept order was arbitrary, capricious, or an abuse of discretion. *Id.* § 706(1). An agency decision meets that description if the agency "entirely failed to consider an important aspect of the problem" or "offered an explanation for its decision that runs counter to the evidence before the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *accord Sierra Club v. EPA*, 939 F.3d 649, 663–64 (5th Cir. 2019). Courts "must set aside any action premised on reasoning that fails to account for 'relevant factors' or evinces 'a clear error of judgment.'" *Data Mktg. P'ship, LP v. DOL*, 45 F.4th 846, 855 (5th Cir. 2022) (quoting *Univ. of Tex. M.D. Anderson Cancer Ctr. v. HHS*, 985 F.3d 472, 475 (5th Cir. 2021) (internal quotation marks omitted)).

Plaintiffs have not shown a substantial likelihood of success on the merits of their APA claim. As to the ten PMTAs uploaded by Skyte, the deficiencies in the original applications exist and are undisputed. But those deficiencies would have been cured by the ten amendments that the FDA rejected. The APA analysis thus turns on the reasons for rejecting those amendments.

The first reason was that one amendment omitted a Form 4057a. But Magellan has introduced evidence that all of its amendments included Form 4057a. Doc. 1 at 10 (verified complaint); Doc. 7-1 at 2 (Huang Decl.). Unless the administrative record ultimately shows otherwise, the FDA's explanation for rejecting that amendment thus runs counter to the evidence before the agency. But any error in misunderstanding the record as to that one application is not prejudicial given that the FDA's second reason (the STN issue) applies to this amendment along with the others. *See* 5 U.S.C. § 706 (judicial review must take account of the rule of prejudicial error).

The FDA's second reason for rejecting the amendments will likely survive final judicial review. The governing regulation on amending a PMTA requires an applicant to include the "STN assigned to the original submission." 21 C.F.R. § 1114.9(a). Of course, if there is no STN assigned to the original submission, then no such STN is required to amend that submission. And if an STN had been assigned within the agency, but the applicant was not on notice that an STN had been assigned, the applicant likewise cannot rationally be expected to supply such an STN as part of an amendment.

But those are not the facts shown here. Magellan's contractor was notified that the eleven original PMTAs had STNs assigned. Indeed, the contractor received a list of those eleven STNs. The issue thus becomes whether it was arbitrary, capricious, or an abuse of discretion to expect Magellan to list the appropriate STN when amending each PMTA. Plaintiffs have not shown a strong likelihood of success on that argument. The exhibits before the court show that the FDA timely responded to Magellan's question in July about STNs. Doc. 26 at 4. There is no evidence showing that the agency was dilatory or nonresponsive, such that it would be arbitrary or capricious to expect Magellan to request any further clarification needed for it to provide the information required by regulation. So the FDA's second reason for rejecting the amendments was likely not arbitrary or capricious. And thus neither was its decision to review the ten Skyte PMTAs as originally submitted, rejecting them based on the two deficiencies noted above.

The third deficiency noted in the refuse-to-accept order goes to the dual-language documents in two PMTAs. The Mandarin passages in those documents are "information." Magellan thus had to provide "complete English translations" of that Mandarin text under the governing regulation. 21 C.F.R. § 1105.10(a)(2). It could be possible that the English text in the documents is itself a complete English translation. But that is not obvious. At least some Mandarin text is not followed by an English passage, as noted above. More broadly, a "complete" translation is required, and Magellan submitted nothing attesting to the completeness of the English text as a

translation of the Mandarin text. The agency did not act arbitrarily or capriciously in requiring documentation of the completeness of the translation. Perhaps that documentation for passages within documents could take a form other than the certificate of translation required for "documents" translated into English. But the record does not show that Magellan submitted anything establishing the completeness of any suggested translation of the Mandarin passages in the dual-language documents.

7. Because plaintiffs have not shown a substantial likelihood of success on the merits, the court denies their motion (Doc. 7) for a preliminary injunction and a temporary restraining order. The court grants defendants' and plaintiffs' unopposed motions to seal (Docs. 20, 27) except as to the limited excerpt reproduced above of the dual-language documents. The court grants plaintiffs' motion for leave to file excess pages (Doc. 24).

Pursuant to the court's prior order (Doc. 32), the parties must file a joint status report within two weeks giving their positions on (1) a new answer or responsive pleading deadline, (2) the need for discovery, and (3) the ability to resolve this case on a motion for summary judgment.

So ordered by the court on September 29, 2023.

J. Campbell Barker
United States District Judge